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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/753,267	01/08/2004	Nancy E. Stagliano	MPI03-003P1RNOMNIM	6532

22907 7590 09/25/2006

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EXAMINER	
VENCI, DAVID J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/753,267	STAGLIANO ET AL.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *August 18, 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply*.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, drawn to a method of screening compounds against a polypeptide, classified in class 435/DIG.15 or class 435/DIG.5, for example.

II. Claims 12-14, drawn to a method of identifying a cardiovascular or thrombotic disorder, classified in class 435/7.1, for example.

III. Claims 15-20, drawn to a method of treating a cardiovascular or thrombotic disorder, classified in class 424/9.2, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I II and III are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the inventions have different modes of operation and different function. For example, Invention I requires screening compounds in order to identify a particular compound. In contrast, Invention II requires performing a diagnostic correlation using a sample from an individual, while Invention III requires administering a drug in order to treat a disease.

Restriction for examination purposes is proper because the inventions are distinct and require separate, non-coextensive searches of the prior art. For example, a prior art search for the method of Invention I requires a search of prior art related to combinatorial assays, while a prior art search for the method of Invention II requires a search of prior art related to clinical marker validation, while a prior art search for the method of Invention III requires a search of prior art related to drug target validation.

This application contains claims directed to the following patentably distinct species:

A. Select ONE polypeptide from: 1722, 10280, 59917, 85553, 10653, 9235, 21668, 17794, 2210, 6169, 10102, 21061, 17662, 1468, 12282, 6350, 9035, 1820, 23652, 7301, 8925, 8701, 3533, 9462, 9123, 12788, 17729, 65552, 1261, 21476, 33770, 9380, 2569654, 33556, 53656, 44143, 32612, 10671, 261, 44570, 41922, 2552, 2417, 19319, 43969, 8921, 8993, 955, 32345, 966, 1920, 17318, 1510, 14180, 26005, 554, 16408, 42028, 112091, 13886, 13942, 1673, 54946, or 2419.

B. Select ONE peptide form from:

a. Isolated; (claim 4)

b. Membrane-bound; OR (claim 4)

c. Cell comprised. (claim 4)

C. Select ONE disorder from:

a. Aberrant vascularization; (claims 5, 10 and 16)

b. Atherosclerosis; (claims 5, 10 and 16)

c. Thrombosis; (claims 5, 10 and 16)

d. Coronary artery disease; (claims 5, 10 and 16)

e. Hyperlipidemia; (claims 5, 10 and 16)

f. Dyslipidemia; (claims 5, 10 and 16)

g. High blood pressure; OR (claims 5, 10 and 16)

h. Heart failure. (claims 5, 10 and 16)

D. Select ONE assay format from:

a. Competition binding assay; (claims 6 and 11)

b. immunoassay; OR (claims 6 and 11)

c. Yeast two-hybrid assay. (claims 6 and 11)

E. Select ONE aberration from:

a. Polypeptide activity; OR (claim 15)

b. Nucleic acid expression. (claim 15)

F. Select ONE modulator from:

a. Polypeptide activity; OR (claim 18)

b. Nucleic acid expression. (claim 20)

Applicants are required under 35 U.S.C. 121 to elect ONE species from each of groups A though F for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently, claims 1, 7, 12 and 15 are generic.

Applicants are advised that a complete reply to this requirement must include: (i) an election of a species or invention to be examined even if the requirement is traversed[1] (37 CFR 1.143), and (ii) identification of the claims encompassing the elected invention.

The species from each of groups A though F are independent or distinct. With respect to group A, the species are independent or distinct by virtue of their unique peptide sequences and chemical structures. With respect to groups B and D, the species are independent or distinct because each of the assay formats require different means and steps for detection, depending on the particular physical form or particular location of the peptide. With respect to group C, the species are independent or distinct because each disease requires a different diagnostic correlation. With respect to groups E and F, the

[1] Applicant may elect an invention or species with traverse or without traverse. To reserve a right to petition, Applicant must elect with traverse. Should Applicant traverse on the ground that the inventions or species are not patentably distinct, Applicant should clearly admit on the record, or submit or identify evidence on the record that the inventions or species are obvious variants. If Examiner finds one Inventions unpatentable over the prior art, Examiner may use the evidence or admission of record to reject other inventions under 35 U.S.C.103(a).

modulator species are independent or distinct by virtue of their unique chemical structures, which necessarily have unique efficacy depending on the particular aberration.

A telephone call was made to Lisa Hemmendinger on September 18, 2006, to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

APPLICANT IS GIVEN ONE MONTH FROM THE DATE OF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R.. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio (**<http://www.uspto.gov/ebc/efs/downloads/documents.htm>**, EFS Submission User Manual - ePAVE)

2. Mailed to:

U.S. Patent and Trademark Office

Box Sequence, P.O. Box 2327

Arlington, VA 22202

Conclusion

Restriction to one of Inventions I through III is required.

Amendment of specification and claims to comply with the Sequence Rules is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David J Venci
Examiner
Art Unit 1641

djv

LONG V. LE 09/18/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Notice to Comply	Application No. 10/753,267	Applicant(s) Stagliano et al.	
	Examiner D. Venci	Art Unit 1641	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: The specification and claims fail to identify sequences by sequence number (*i.e.*, SEQ. ID. NOS:) that correspond to those sequences submitted on Computer Readable Form (CRF) and recited in the Sequence Listing. Reference to sequence number (*i.e.*, SEQ. ID. NOS:) in the claims is required prior to search and examination.

Applicant Must Provide:

☐ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☐ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-2510
For CRF Submission Help, call (571) 272-2501/2583.
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